K111114 P1/2

MAY 20 2011

510K Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. The submitter of this pre-market notification is:

Kristen Lessard
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This summary was prepared on April 13, 2011

2. The name of the subject device is the Philips SureSigns VS2$^+$ Vital Signs Monitor.

3. The trade name of the device is the SureSigns VS2$^+$ Vital Signs Monitor.

4. The common usual name is multi-parameter patient monitor

5. The Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular	870.1110, II	DSJ	Alarm, Blood Pressure
	870.1110, II	DSK	Computer, Blood Pressure
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive
	870.1435, II	DXG	Computer, Diagnostic, Pre-programmed, Single function
	870.2700, II	DQA	Oximeter
	870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient connector
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical

6. The modified device is substantially equivalent to previously cleared Philips device, SureSigns VS2 Patient Monitor marketed pursuant to 510(k) K082280 cleared for software revision A.00 and under 510(k) K090483.

7. This submission is to introduce a new model, the Philips SureSigns VS2$^+$ Vital Signs Monitor that compliments the existing VS2/VS3 Vital Signs monitors.

8. The subject device has the same intended use and indications for use as the legally marketed predicate device. The SureSigns VS2$^+$ Vital Signs monitor is for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Standard and optional parameters include: NBP, SpO2, and Temperature. Intended for monitoring, recording, and alarming of multiple physiological parameters of adults,

pediatrics and neonates in healthcare environments. Additionally, the monitors may be used in transport situations within a healthcare facility.

9. The subject device has the same fundamental technological characteristics as the legally marketed predicate device. The subject device use the same design as the predict device. The energy source of the subject device is an internal power supply. The VS2$^+$ can run on battery power with batteries similar to the predicate device, however, with improved battery life.

10. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device, the specifications of the subject device and test results showed substantial equivalence. The results demonstrate that the Philips SureSigns VS2$^+$ Vital Signs monitor meets all reliability requirements and performance claims and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Philips Medical Systems.
c/o Ms. Kristen Lessard
Quality & Regulatory Engineer
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810

MAY 2 0 2011

Re: K111114
Trade/Device Name: SureSigns VS2$^+$ Vital Signs Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Codes: DXN, DQA, DSJ, DSK, DXG, DSA, FLL
Dated: April 15, 2011
Received: April 21, 2011

Dear Ms. Lessard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (if known): K111114

Device Name: SureSigns VS2$^+$ (reference numbers: 863278, 863279)

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

Standard and optional parameters include:

- NBP
- SpO2
- Temperature

Prescription Use: YES AND/OR over-the-counter Use: NO
(Part 21 CFFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111114